DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

1011 5 MAY 13 P2:32

MAY - 5 2005

Ms. Erin Silva
Technical Marketing Associate
Anabolic Laboratories, Inc.
26021 Commerce Centre Drive
Lake Forest, California 92630

Dear Ms Silva:

This is in response to your letter of April 4, 2005 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The products **Mega Omega 3** is using the claim "May reduce the Risk of coronary Heart Disease." The product **CholestFighter** is using the claim "Clinically Proven to Reduce Cholesterol". These statements are not claims subject to 21 U.S.C. 343(r)(6), but claims subject to 21 U.S.C. 343(r)(1)(B) because they represent that the products will reduce the risk of a disease or health related condition (i.e., coronary heart disease). FDA has authorized a health claim about the relationship between phytosterol and phytostanol esters and coronary heart disease (see 21 CFR 101.83)[1]. FDA has also issued letters defining the conditions in which it would exercise enforcement discretion with respect to the use of a qualified health claim for dietary supplements containing omega-3 fatty acids.[2] A dietary supplement that meets the eligibility and message requirements set forth in the regulation (or enforcement discretion letters, if applicable) may bear a claim for the relationship between phytosterol/stanol esters and coronary heart disease or omega-3 fatty acids and coronary heart disease. A health claim on the label or in the labeling of a food or dietary supplement that is not in accordance with the requirements in 21 CFR 101.83 or in the case of a product containing omega-3 fatty acids, the relevant enforcement discretion letters, would misbrand the food or dietary supplement under 21 U.S.C. 343(r)(1)(B). Moreover, failure to make a claim in accordance with the requirements in

[1]Also see February 14, 2003 letter regarding enforcement discretion with respect to expanded use of an interim health claim rule about plant sterol/stanol esters and reduced risk of coronary heart disease; http://www.cfsan.fda.gov/~dms/ds-ltr30.html.

[2]See letters regarding enforcement discretion with respect to use of qualified health claims about reduced risk of coronary heart disease; http://www.cfsan.fda.gov/~dms/lab-qhc.html.

21 CFR 101.83 or the applicable enforcement discretion letter subjects the product to regulation as a drug under 21 U.S.C. 321(g)(1)(B) because the product is intended to treat, cure, prevent, or mitigate a disease, coronary heart disease.

Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

APR 2005

April 4, 2005

Susan J. Walker, M.D.
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food & Drug Administration
200 C Street SW
(HFS-450)
Washington, D.C. 20204

Dear Dr. Walker:

This letter is to notify you, as per section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA) that Anabolic Laboratories, Inc. is offering for sale Mega Omega 3, as a dietary supplement. It contains the following structure/function statement: "May Reduce the Risk of Coronary Heart Disease" as it contains 600mg fish oil per serving. This will be sold as a mass market product and the label contains the proper disclaimer as well.

Thank you,

Erin Silva, MS, RD, CNSD
Technical Marketing Associate

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APR 2005

April 4, 2005

Susan J. Walker, M.D.
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food & Drug Administration
200 C Street SW
(HFS-450)
Washington, D.C. 20204

Dear Dr. Walker:

This letter is to notify you, as per section 6 of the Dietary Supplement Health and Education Act of 1994 (DSHEA) that Anabolic Laboratories, Inc. is offering for sale CholestFighter, as a dietary supplement. It contains the following structure/function statement: "Clinically Proven to Reduce Cholesterol". This product contains the exact same amount of plant sterols (900mg per two capsules; at least 88% combined phytosterols—meeting the content as required by 21 CFR 101.83) and the same structure/function claim used by the approved Nature Made® "Cholest-Off" dietary supplement. This will be sold as a mass market product and the label contains the proper disclaimer as well.

Thank you,

Erin Silva, MS, RD, CNSD
Technical Marketing Associate

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